

REMARKS

Status of the claims

Claims 9-12 and 14-16 are pending in the application. Claim 9 has been amended to be in independent form and claims 10 and 11 correspondingly amended to depend from claim 9. Claim 1 has been cancelled herein and claims 2-8 and 13 were previously cancelled. New claims 14-16 have been added. Support for new claims 14-16 may be found in claim 9. No new matter has been added by way of the above amendments.

Rejections under 35 U.S.C. §112, 1st paragraph

Claims 11 and 12 have been rejected under 35 U.S.C. 112, first paragraph for lack of enablement. The Examiner appears to base the rejection on the breadth of compounds encompassed by claim 1, from which claims 11 and 12 depended. Claim 1 has been cancelled herein and claims 11 and 12 have been amended to depend from claim 9, which recite only three specific compounds. As such, the scope of the claims has been significantly more defined and is fully enabled. Withdrawal of the rejection is, therefore, respectfully requested.

Obviousness-type double patenting rejections

Claims 1 and 10-12 have been rejected under the judicially created doctrine of obviousness-type double patenting for being obvious over the following issued patents and pending applications.

- 1) Claims 1-15 of USP 6,297,261
- 2) Claims 1-13 of USP 6,696,475
- 3) Claims 12-20 of published application No. 2006/0058395
- 4) Claims 21-39 of published application No. 2006/0160856
- 5) Claims 11 and 12 have been further rejected for obviousness-type double patenting as being obvious over claims 1-41 of published application No. 2007/0293553.

Applicants traverse the rejections over USP 6,297,261, USP 6,696,475, published application No. 2006/0058395 and published application No. 2006/0160856, and withdrawal thereof is respectfully requested.

The instant invention as been defined in claim 9 as being directed to the following compounds,

N-(3,5-Difluoro-phenyl)-*N'*-[3-(1*H*-tetrazol-5-yl)-3'-trifluoromethyl-biphenyl-4-yl]-urea;

N-(3,5-Dichloro-phenyl)-*N'*-[3-(1*H*-tetrazol-5-yl)-3'-trifluoromethyl-biphenyl-4-yl]-urea;

N-(3,5-Bis-trifluoromethyl-phenyl)-*N'*-[3-(1*H*-tetrazol-5-yl)-3'-trifluoromethyl-biphenyl-4-yl]-urea; or a pharmaceutically acceptable salt thereof.

All of the instant compounds thus have a 3'-trifluoromethyl-substituted biphenyl group. There is no disclosure in any of the cited references for making specifically a trifluoromethyl substitution as required with the instantly claimed compounds. As the Court of Appeals for the Federal Circuit held in *Takeda Chemical Industries Ltd. v. Alphapharm Pty. Ltd.*, 83 USPQ2d 1169 (Fed. Cir. 2007), subsequent to the Court's decision in *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007), "In addition to a structural similarity between the compounds, a *prima facie* case of obviousness also requires a showing of "adequate support in the prior art" for the change in structure." Thus, in cases involving new chemical compounds, it remains necessary to identify some reason that would have led a chemist to modify a known compound in a particular manner to establish *prima facie* obviousness of a new claimed compound." No reason has been provided for why one skilled in the art would make the specific modification of having a 3'-trifluoromethyl substituent on the biphenyl group. As such, no *prima facie* case of obviousness has been established and withdrawal of the obviousness-type double patenting rejection is respectfully requested.

The present invention is further not obvious as evidenced by the attached declaration of Dr. Palle Christophersen, submitted under 37 C.F.R. §1.132. In the declaration, a comparison was done between the claimed compound *N*-(3,5-Dichloro-phenyl)-*N'*-[3-(1*H*-tetrazol-5-yl)-3'-trifluoromethyl-biphenyl-4-yl]-urea and *N*-(3,5-Dichloro-phenyl)-*N'*-[4'-carboxamid-2-(1*H*-tetrazol-5-yl)-4-biphenyl urea from US 2006/0160856 and the following three compounds of USP 6,297,261, USP 6,696,475, and US 2006/0058395:

N-(3-Trifluoromethylphenyl)-N'-(4'-carboxy-2-(1-H-tetrazol-5-yl)-4-biphenyl) urea

3-Trifluoromethylphenyl-4-phenyl-2-(5-tetrazolyl)phenyl urea

3-Trifluoromethylphenyl-4-(4-aminocarbonylphenyl)-2-(5-tetrazolyl)phenyl urea

As demonstrated by the attached declaration the compounds of the instant invention possess unexpected improved activity compared to the compounds in any of USP 6,297,261, USP 6,696,475, US 2006/0058395 or US 2006/0160856. As such, withdrawal of the double patenting rejections over any of Claims 1-15 of USP 6,297,261; Claims 1-13 of USP 6,696,475; Claims 12-20 of published application No. 2006/0058395 and Claims 21-39 of published application No. 2006/0160856 are respectfully requested.

With regard to the rejection of claims 11 and 12 for obviousness-type double patenting over claims 1-41 of US2007/0293553, Applicants note that the '553 publication was filed subsequently to the instant application. Applicants request that this rejection be held in abeyance until the claims in one of the two applications are otherwise patentable.

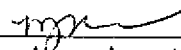
In view of the above amendment and Remarks, Applicant believes the pending application is in condition for allowance.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact MaryAnne Armstrong, Ph.D., Reg. No. 40,069 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

Dated: November 17, 2008

Respectfully submitted,

By 
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Attachment: Declaration of Dr. Palle Christophersen